

3529. Adulteration and misbranding of conjugated estrogens. U. S. v. 5 Bottles * * *. (F. D. C. No. 30949. Sample No. 6874-L.)

LIBEL FILED: May 8, 1951, Southern District of New York.

ALLEGED SHIPMENT: On or about April 9, 1951, from Pittsburgh, Pa. This was a return shipment.

PRODUCT: 5 1,000-tablet bottles of *conjugated estrogens* at New York, N. Y. Examination showed that the total amount of estrogens actually present per tablet calculated to 0.69 mg., expressed as a mixture of sodium estrone sulfate and sodium equilin sulfate.

LABEL, IN PART: "Tablets Water Soluble Conjugated Estrogens * * * Robin Pharmacal Corp. New York, N. Y."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 1.25 mgm. of estrogens in their water-soluble form, expressed as sodium estrone sulfate and sodium equilin sulfate.

Misbranding, Section 502 (a), the label statement "Each tablet contains 1.25 Mgm. of estrogens in their naturally occurring water-soluble conjugated form, expressed as sodium estrone sulfate and sodium equilin sulfate" was false and misleading as applied to an article which contained a total amount of estrogens per tablet which calculated to 0.69 milligrams of a mixture of sodium estrone sulfate and sodium equilin sulfate.

DISPOSITION: July 31, 1951. The libel proceedings in the instant case having been removed to the Eastern District of New York and having been consolidated with two other cases relating to the same product, and International Hormones, Inc., Brooklyn, N. Y., claimant, having consented to the entry of a consolidated decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling of the containers, crushing of the tablets, and extraction of the hormones, with subsequent relabeling to insure compliance with the law.

3530. Adulteration and misbranding of conjugated estrogens. U. S. v. 1 Bottle * * *. (F. D. C. No. 30769. Sample No. 23102-L.)

LIBEL FILED: March 13, 1951, District of New Jersey.

ALLEGED SHIPMENT: On or about December 29, 1950, by Success Chemical Co., Inc., from Brooklyn, N. Y.

PRODUCT: 1 1,000-tablet bottle of *conjugated estrogens* at Bloomfield, N. J. Analysis showed that the product contained a total amount of estrogenic steroids calculated to 0.74 mg. of sodium estrone sulfate per tablet.

RESULTS OF INVESTIGATION: According to the consignee, the bottle of *conjugated estrogens* was damaged when received, and the product was transferred by him to another bottle labeled "Premarin Tablets."

LABEL, IN PART: (Bottle, when shipped) "Tablets Conjugens (Conjugated Estrogens) 1.25 mg. Distributed by Success Chemical Co., Inc., Brooklyn, N. Y."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely 1.25 mg. of estrogens in their naturally occurring water-soluble conjugated form, expressed as sodium estrone sulfate.

Misbranding, Section 502 (a), the statement which appeared on the bottle label when shipped, namely, "Each tablet contains 1.25 mgm. of Estrogens in